EXHIBIT B

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 10/023,437	)
Applicant	: Stephen A. Johnston et al.	)
Filed	: December 17, 2001	)
Title	: Methods and Compositions For Vaccination Comprising Nucleic Acid and/or Polypeptide Sequences Of Chlamydia	)
TC/A.U.	: 1645	)
Examiner	: Vanessa L. Ford	)
Docket No.	: 5171-00041	)

CERTIFICATE OF EFS WEB FILING

I hereby certify that this correspondence is being electronically filed via the USPTO Electronic Filing System (EFS Web) on this 18th day of April, 2007.

Marlene Kubiak 04/18/07
Marlene Kubiak Date

DECLARATION OF DR. BERNHARD KALTENBOECK UNDER 37 C.F.R. §1.132

Commissioner of Patents
Mail Stop - AF
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

COMES NOW Dr. Bernhard Kaltenboeck and declares as follows:

1. I am a tenured Professor of Veterinary Medicine at the College of Veterinary Medicine of Auburn University, in Auburn Alabama, USA. I earned my DVM degree in 1976 and my Dr. med. vet. degree in 1977 from the Veterinary Medical University in Vienna, Austria. Between 1977 and 1987, I gained extensive experience in food animal practice with emphasis on dairy cattle. I received my Doctor of Philosophy degree from Louisiana State University under the guidance of Dr. Johannes Storz. In addition to several national honors for publications resulting from my doctoral research, I received the Distinguished Dissertation Award for 1991 from Louisiana State University for my dissertation, "PCR amplification of chlamydial MOMP genes: detection, sequence analysis and evolution". After a 2-year tenure at

the Veterinary Medical University in Vienna, Austria, I joined the faculty at Auburn University in 1994.

2. I am a named inventor on the above-identified patent application, U.S. Patent Application No. 10/023,437 filed on December 17, 2001, by Stephen A. Johnson et al. and find that the invention currently claimed in this patent application is for a method of immunizing an animal by administering a Chlamydia antigen having particular nucleotide or peptide sequences.

3. I have reviewed the Office Action mailed February 8, 2007. By the present declaration I will set forth why the claims are enabled, and particularly how the data of Figure 5 includes enabling disclosure.

4. In the second full paragraph on page 4 of the office action, the Examiner states: "[t]he instant specification discloses in examples 5-12 experimental examples using *Chlamydia* nucleic acid molecules and polypeptides used to immunize animals. The specification refers Figures 4-8 which disclose the data from the various experimental examples." However, I would also like to note that Example 1 and Figures 2-3 demonstrate an exemplary ELI protocol. In this respect and in relation to Figure 5, the application states (p.66:29-67:6): "In the fourth round, the animals received two boosts rather than one, and the challenge inoculum was increased...to increase the selectivity of protection scoring. Furthermore, because too much DNA may lead to a decrease in cellular immune response, the amount of each individual clone was reduced by half...The inventors also decreased the gene gun in the same manner...Mice were boosted i.m. at both four and nine weeks after prime inoculation, and were challenged. The results of this final round are depicted in FIG. 5."

5. Turning now to Figure 5, the experiment of Figure 5 was designed as follows. First, groups of mice (1-14) were genetically immunized with constructs that contained *C. psittaci* DNA inserts that coded for open reading frames of more than 50 amino acids, that had been identified in previous rounds of the screen as described at p.70-72 of the application, and were considered potential vaccine candidates. We, the inventors, made the reasonable

assumption that the inserts were in the correct coding frame because they coded for peptides that were longer than 50 amino acids. It is highly unlikely that incorrect open reading frames would code for such long peptides, because open reading frames of random, incorrect inserts would be terminated much earlier, i.e. before 50 amino acids (AA), by a random stop codon.

6. The control groups for the genetic immunization were designed to imitate, as closely as possible, the presumably correct inserts. To that end, all vaccine plasmids from the previous round that contained presumably correct coding inserts of more than 50 amino acids were pooled and considered the positive control for genetic immunization [pool (>50 AA)]. All vaccine plasmids with inserts coding for peptides of less than 50 amino acids were considered random irrelevant clones and pooled into another control group and considered the negative control for genetic immunization [pool (<50 AA)].

7. Two other groups of control mice did not receive any genetic immunization and were considered calibration controls that allowed determining the amount of immune protection achievable under conditions of natural infection without vaccination. The first group was labeled "Vaccinated," and contained mice that received a low-dose intranasal inoculation with *C. psittaci* 4 weeks prior to the high-dose challenge. This low-dose inoculation did not cause disease but elicited strong specific immunity against *C. psittaci*. The effect of this low-dose challenge was that these mice showed immunity equivalent to previous natural infection and were highly protected against the high-dose challenge with *C. psittaci* 4 weeks later. The immune protection of this group from the high-dose challenge infection was considered the highest possible naturally protective immunity and arbitrarily set at a protection score of 1 (100% protection).

8. To calibrate the range of protection, a second group of mice designated as "Challenged" was used. These mice received a sham inoculum 4 weeks prior to the high-dose *C. psittaci* challenge, and thus were completely un-exposed to *C. psittaci* (immunologically naïve) prior to high-dose challenge, and were considered non-protected from the challenge infection. The immune protection of this group from the high-dose challenge infection was

considered the lowest possible protective immunity and arbitrarily set at a protection score of 0 (0% protection). Thus, the "Challenged" group provides a "non-vaccinated...negative control" as it provides a basis for the relative protection score.

9. The interpretation of the results demonstrated in Figure 5 indicates that:

i) genetic immunization constructs 1-5 of more than 50 AA coding inserts achieved protection from *C. psittaci* better than that achievable with previous low-dose natural infection;

ii) the positive genetic immunization control pool (>50 AA) of all assumed correctly coding genetic immunization constructs also protected better than protection naturally achievable; and, importantly,

iii) the negative genetic immunization control pool (<50 AA) of all incorrect coding constructs did not protect the mice.

10. The undersigned hereby declares that all statements made herein are of his own knowledge, are true and that all statements made on information are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent.

Dated: April 17, 2007

Bernhard Kaltenboeck

Dr. Bernhard Kaltenboeck